



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,831	01/04/2002	Ralph Weissleder	00786-527001	9546

26161 7590 06/26/2003

FISH & RICHARDSON PC  
225 FRANKLIN ST  
BOSTON, MA 02110

EXAMINER

JONES, DAMERON L

ART UNIT PAPER NUMBER

1616

DATE MAILED: 06/26/2003

2

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/039,831

Applicant(s)

WEISSLEDER ET AL.

Examiner

D. L. Jones

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-53 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7 and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by phosphorylation/dephosphorylation, classified in class 424, subclass 1.11+.
  - II. Claims 1-3, 10, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by receptor-mediated binding, classified in class 424, subclass 1.45.
  - III. Claims 1-3, 11-13, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe contains a receptor polypeptide, classified in class 424, subclass 1.69.
  - IV. Claims 1-3, 14-16, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated removal of the functional group, classified in class 424, subclass 94.1+.
  - V. Claims 1-3, 17-20, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated splicing, classified in class 424, subclass 94.1+.
  - VI. Claims 1-3, 21, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated transfer of a chromophore, classified in class 424, subclass 94.1+.

- VII. Claims 1-3, 22-24, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe contains a nucleic acid sequence specific for a recombinase, classified in class 424, subclass 1.11+.
- VIII. Claims 1-3, 25-28, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe contains a transmembrane signal, classified in class 424, subclass 1.11+.
- IX. Claims 1-3, 29-31, and 34-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by hybridization of a nucleic acid sequence to a complementary targeting nucleic acid, classified in class 424, subclass 1.73.
- X. Claims 1-3 and 32-54, drawn to a probe composition and in vivo methods thereof wherein the probe is activated upon binding of the probe to an analyte, classified in class 424, subclass 1.11+.
- XI. Claims 1-7 and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by phosphorylation/dephosphorylation, classified in class 435, subclass 194.
- XII. Claims 1-3, 10, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by receptor-mediated binding, classified in class 435, subclass 7.1.
- XIII. Claims 1-3, 11-13, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe contains a receptor polypeptide, classified in class 8, subclass 563.

- XIV. Claims 1-3, 14-16, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated removal of the functional group, classified in class 435, subclass 814+.
- XV. Claims 1-3, 17-20, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated splicing, classified in class 435, subclass 183+.
- XVI. Claims 1-3, 21, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by enzyme-mediated transfer of a chromophore, classified in class 435, subclass 193.
- XVII. Claims 1-3, 22-24, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe contains a nucleic acid sequence specific for a recombinase, classified in class 536, subclass 22.1+.
- XVIII. Claims 1-3, 25-28, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe contains a transmembrane signal, classified in class 210, subclass 500.22.
- XIX. Claims 1-3, 29-31, and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated by hybridization of a nucleic acid sequence to a complementary targeting nucleic acid, classified in class 435, subclass 6+.
- XX. Claims 1-3 and 55, drawn to a probe composition and in vivo methods thereof wherein the probe is activated upon binding of the probe to an analyte, classified in class 378, subclass 44.

**Note:** Claims appearing in more than one group will only be examined to the extent that the claims read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions I-XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions have different modes of operation. In particular, the probes necessary for each group operates by a different mechanism as set forth above. Also, it is noted that the methods may be used for in vivo or in vitro purposes. Furthermore, it should be noted that prior art anticipating or rendering obvious one group above would neither anticipate nor render obvious another group.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

#### **ELECTION OF SPECIES**

4. This application contains claims directed to the following patentably distinct species of the claimed invention. The various probes as set forth in Groups I-XX above which may comprise one or more chromophore (see claim 3); have various optical properties (see claim 2); may comprise a transmembrane signal sequence (see claim

Art Unit: 1616

28); may comprise an analyte (see claim 33), may be used to detect various diseases (see claim 39); or may have different means of performing the illuminating or detecting steps (see claim 54).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is respectfully requested to elect a single disclosed species from within the elected group for search purposes. The species should contain (if applicable) the following components, chromophore(s) (see claim 3); optical properties (see claim 2); transmembrane signal sequence (see claim 28); analyte (see claim 33); disease detected (see claim 39); how illuminating/detecting steps are performed (see claim 54).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Due to the complexity of the restriction requirement, no telephone call was made to request an oral election to the above restriction requirement.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (703) 308-4640. The examiner can normally be reached on Mon.-Fri. (alternate Mon.), 6:45 a.m. - 4:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose' Dees can be reached on (703) 308- 4628. The fax phone numbers

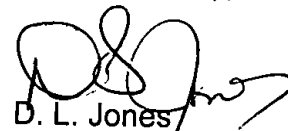
Application/Control Number: 10/039,831

Page 8

Art Unit: 1616

for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



D. L. Jones  
Primary Examiner  
Art Unit 1616

June 24, 2003